UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,938	09/13/2005	Piero Del Soldato	026220-00058	8653

4372 7590 09/09/2008

ARENT FOX LLP
1050 CONNECTICUT AVENUE, N.W.
SUITE 400
WASHINGTON, DC 20036

EXAMINER	
BIANCHI, KRISTIN A	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
09/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)	
	10/516,938	DEL SOLDATO ET AL.	
	Examiner	Art Unit	
	KRISTIN BIANCHI	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/15/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *2, 3, 6-8, 10, and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,9,11 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/2004 and 06/01/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in the instant application. Claims 2, 3, 6-8, 10, and 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected subject matter. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference which anticipates one group would not render obvious the other. Claims 1, 4, 5, 9, 11, and 21-23 are rejected.

Information Disclosure Statement

The information disclosure statements submitted on December 14, 2004 and June 1, 2005 were considered and copies of form 1449 are submitted herewith.

Election/Restrictions

Applicants' amendment to the claims submitted on July 15, 2008 has been considered and entered into the application. Applicants' election with traverse of Group I and the compound N-[4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]phenylsulfonyl]-4-nitroxy-butanamide in the response filed on July 15, 2008 was considered. The traversal is made on the ground(s):

"As an application subject to PCT Rule 13, Applicants submit that they are entitled to "an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of said product, and an independent claim for a use of the said product" for prosecution in the present application (MPEP § 1850 (111)(1))."

This argument is not found to be persuasive. The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a):

"Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical

features... those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

The technical feature linking the claims in this application (i.e. the NO2 group) is not a special technical feature because it fails to define a contribution over the prior art as was presented in the restriction requirement dated June 17, 2008. Therefore, the claims are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the technical feature present fails to define a contribution over the prior art. Additionally, the variables found on the technical feature can vary and when taken as a whole result in structurally different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity on invention is considered to be proper.

Restriction of the invention in accordance with the rules of unity of invention is therefore made FINAL.

The traversal of the election of species requirement is on the ground(s):

"… the compounds of the invention are all derivatives of drugs belonging to the same therapeutic class of COX-2 selective inhibitors and can be synthesized using the general methods reported in the application (see pages 12-14 of WO 2004/000781)."

This argument is not found to be persuasive. As stated in the restriction requirement dated June 17, 2008, the species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species lack the same or corresponding special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

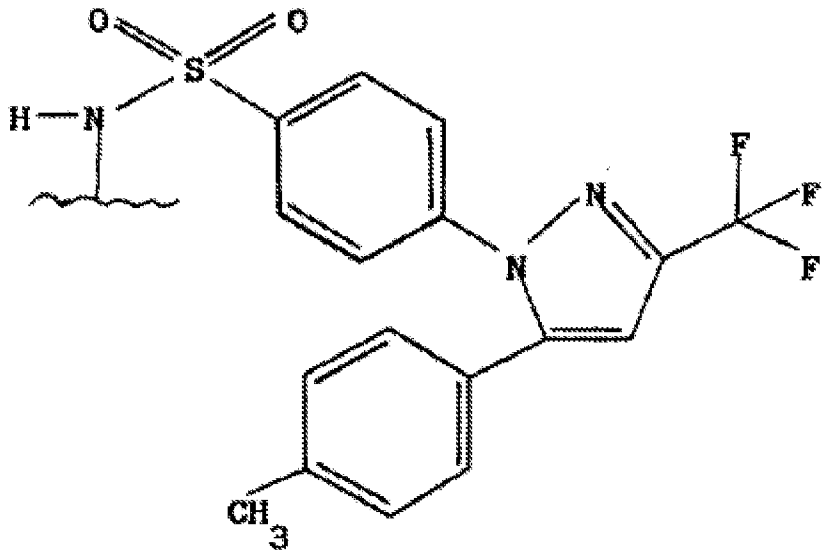
Claims 1, 4, 5, 9, 11, and 21-23 are rejected under 35 U.S.C. 103(a) as being obvious over WO 98/09948 in view of Mamidi et al. further in view of WO 00/61541.

The applied references (i.e. WO 98/09948 and WO 00/61541) have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130

stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Determination of the scope and contents of prior art.

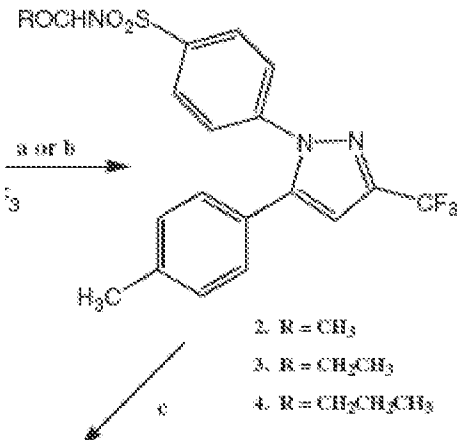
WO 98/09948 discloses compounds and compositions (i.e. for the preparation of medicaments) of the general formula A–X1-NO2 where A = R(COX)t and where t is an integer 0 or 1 (abstract), such as COX2 inhibitors where t =O and R is



(page 24).

X1 is equal to –YO- where Y can be C1-C20 alkylene, preferably having from 2 to 5 carbon atoms (pages 38-39).

Mamidi et al. discloses a COX2 inhibitor of the following formula (page 275):



wherein R is CH2CH2CH3. The prodrug form of this compound was administered to rats orally.

WO 00/61541 disclose compounds and pharmaceutical formulations of the formula A-Bbo-C-N(O)s wherein s is 2, A is R-T1 where R is a drug radical (i.e. an antiinflammatory drug or non steroid antiinflammatory drug, pages 3 and 4 and claims 8 and 9), T1 is (CO)t where t is 1, bo is 0, C is –Tc-Y- where Tc is (CO) or X, and Y or Y0 is an alkylenoxy group R'O wherein R' is linear C1-C20, preferably having from 1 to 6 carbon atoms.

Ascertaining the differences between prior art and instant claims.
WO 98/09948 discloses COX2 inhibitors which differ from the elected compound of the instant claims by not having a carbonyl group attached to the nitrogen of compound V Ac4 (i.e. t is 0). This missing carbonyl group would correspond to the Tc =CO group of the instant claims.

Mamidi et al. discloses a COX2 inhibitor which differs from the elected compound of the instant claims by not having a -ONO2 group attached at the end of the alkyl chain.

WO 00/61541 discloses compounds with non steroid anti-inflammatory drugs (claims 8 and 9) which differ from the elected compound of the instant claims by having an extra CO or O, S or NR1c (i.e. Tc) in the compounds.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
Since the compounds and compositions disclosed in the three references are all used as COX2 inhibitors, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the compound disclosed in WO 98/09948 and add a carbonyl (i.e. between the nitrogen and the C1-C20 alkylene group) since a carbonyl is present (i.e. between the nitrogen and the

CH2CH2CH3 group in Mamidi et al. and attached to the non steroid anti-inflammatory drug in WO 00/61541) in the other two references.

One of ordinary skill would be motivated to make the modification required to arrive at the instant invention with reasonable expectation of success for obtaining a compound with the same activity. The motivation to make the claimed compound would be to make additional compounds for the quoted purpose.

Thus, the instant claims are *prima facie* obvious over the teachings of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626

Kristin Bianchi
Examiner
Art Unit 1626

***